Tangential Speculation and the Regulatory Investigation

November 6, 2012

Regulatory compliance is measured by completing licensing inspections. Most licensing inspections are initiated by statutory or regulatory requirements. The most common example of this is the need to conduct a renewal inspection to determine whether a licensed setting continues to meet the requirements for licensure. The regulator's method of conducting such inspections is one of *neutral evaluation*: the regulator does not hypothesize compliance or noncompliance with the regulations, but rather uses information gathered and analyzed during the inspection process to conclusively establish compliance or noncompliance.

There are also inspections that are initiated in response to a specific event such as a complaint or an incident self-reported by a licensed setting. These inspections are called *regulatory investigations*. The regulator's goal in completing a regulatory investigation is not to determine whether or not an event occurred; it is to determine whether the setting was in compliance with regulatory requirements associated with an event, if the event occurred. This is not to say that the evidence collected by the regulator will not verify the occurrence of an event, or that the regulator should avoid verifying that an event occurred. Indeed, the regulatory investigation will frequently substantiate whether or not something happened, but only as a side-product of establishing compliance. This is so because compliance and noncompliance are not necessarily (or usually) dependent on an actual event.

Regulatory investigations require an alternative method of conduct known as *tangential speculation*. Tangential speculation is the practice of associating events with regulations either directly or indirectly. The sequence of tangential speculation is as follows:

1. Notification. The licensing agency becomes aware of one or more events at a setting (e.g., a complaint). Each event consists of sub-events, called elements, which occur in a series. For the purposes of completing the tangential speculation sequence, each element is assumed to be true.

2. Initial Analysis. Each element is analyzed to determine: what information is needed to corroborate or abrogate the element (*Corroborated* means that the element is accurate or partially accurate as reported in the event. *Abrogated* means that the element did not occur); whether the element, if corroborated, directly relates to a regulatory requirement; and whether the element, if corroborated, indirectly relates to a regulatory requirement, e.g., if the element exists within certain conditions that could be regulatory.

3. Plan. An investigation plan is developed. The investigation plan includes identifying the members of the investigation team; establishing the practical means of gathering the information needed to corroborate or abrogate the element, including but not limited to direct observation of the setting's physical plant, interviews, review of documents produced by the setting and by third parties; and assigning responsibility for gathering the required information.

4. Implementation. The investigation plan is implemented.

5. Modification. The investigation plan is modified based on the identification of previously-unknown events identified through the implementation of the investigation plan.

6. Timeline. An event timeline is created, in which the order of the element series is established, and the corroborating information used to establish the order of the element series is mapped to each documented element.

7. Timeline Analysis. The event timeline is analyzed to determine whether regulatory violations related to the original report exist; whether regulatory violations unrelated to the original report exist; or if additional information is required before the existence of violations can be conclusively established.

8. Final Report. A final report of conclusive regulatory findings and the basis for those findings is produced.

At first read, the sequence seems to reflect the standard practice in any kind of investigation: receive allegation, figure out what needs to be done to prove or disprove allegation, do it, and report the outcome. What distinguishes tangential speculation from standard investigation techniques is the above-mentioned independence of regulatory compliance from the veracity of an event. Since the operation of licensed settings is governed by regulatory

requirements, regulatory compliance is the expected norm in licensed settings. Therefore, when an event is reported, the regulator's response is to establish whether the event constitutes a deviation from the norm, and if it does, where to look for it in a licensed setting's operational flow. The regulator *speculates* about the regulations that are *tangential* to an event. If a child care regulator is told, "the worker left my son alone in a room last week," she does not begin her investigation by planning how to verify if the child was left alone, but rather by considering the collection of expectations surrounding a child care center's operation: staff will not leave children alone, they will know not to leave children alone because they have been trained not to leave children alone, and they will not have to leave children alone because there are enough staff to ensure proper supervision at all times. Thus, the key questions of the investigation are, "does the center have enough staff on duty, and are they properly trained?"

The reader will also recognize in tangential speculation the potential for endless investigation – since the operation of licensed settings is connected to regulatory requirements, and since regulatory requirements are connected to one another, it is theoretically possible for investigations to become perpetual feedback loops. Regulatory investigations stop when:

1. Compliance or noncompliance with the regulations that have a direct relationship to the initial notification has been established, and

2. Compliance or noncompliance with the regulations that have an indirect relationship to the initial notification has been established, and

3. Further investigation would require *tertiary speculation*. Tertiary speculation means hypothesizing other potential area of noncompliance absent an empirical motivating element. Following the example above, let us say that the child care investigator has found that the center has sufficient staff on duty, and that they are properly trained, but by and through the investigation she has discovered a discrepancy in the training record that leads her to suspect possible forged documents. The discrepancy is an empirical motivating element, and the investigation should continue. Now let us say that the inspector has a "gut feeling" or intuitive sense that the training record is falsified, but does not have a means to empirically verify this suspicion. To proceed is to engage in tertiary speculation, and is not appropriate for a regulatory investigation. This is not to say, however, that the intuitive sense should always be ignored; the investigator can and should recommend an in-depth review of training documentation during the next licensing inspection initiated by statutory or regulatory requirements.

Tangential speculation is best understood by studying its practical application; in fact, when considered in context, many regulators may recognize that they already apply the technique. Consider the Case Study below, which is based on an actual investigation.

Background

The Commonwealth of Pennsylvania licenses and inspects personal care homes, residential facilities serving four or more adults who require assistance or supervision in activities of daily living. The services of a personal care home can range from simple activities such as helping residents to obtain clean clothing to more extensive assistance like help with bathing and dressing. Personal care homes must comply with 55 Pa.Code Chapter 2600 (relating to personal care homes) in order to receive and retain licensure.

Stage 1: Notification

On June 5, 2010, the licensing agency received the following anonymous complaint:

Food at the home is bad and is normally served cold. Someone lives in the home's basement, which is like a dungeon, dark, cold, and poorly-lit, especially in the hallways. The person has breathing issues and does not receive his breathing treatments, and has problems climbing the steps to receive his medications at 5:30 AM. The resident suffers from weak legs and is in need of therapy, but is not receiving it. He needs a higher level of care.

Stage 2: Initial Analysis

Element	Corroboratory Information Required	Direct Regulatory Relationship 55 Pa. Code Ch. 2600	Indirect Regulatory Relationship 55 Pa. Code Ch. 2600
Food is bad	Manner in which food is stored and provided	161(a) - Meals shall be offered that meet the recommended dietary allowances established by the United States Department of Agriculture. 161(b) - At least three nutritionally well-balanced meals shall be offered daily to the resident. Each meal shall include an alternative food and drink item from which the resident may choose.	85(a) - Sanitary conditions shall be maintained. 103(c) - Food shall be protected from contamination while being stored, prepared, transported and served. 103(i) - Outdated or spoiled food or dented cans may not be used.
Food is cold	Food service practices	None	42(c) - A resident shall be treated with dignity and respect.
Resident lives in hazardous environment	Living conditions in basement area	83(a) - The indoor temperature, in areas used by the residents, must be at least 70°F when residents are present in the home. 87-The home's rooms, hallways, interior stairs, outside steps, outside doorways, porches, ramps, evacuation routes, outside walkways and fire escapes shall be lighted and marked to ensure that residents, including those with vision impairments, can safely move through the home and safely evacuate. 88(a) - Floors, walls, ceilings, windows, doors and other surfaces must be clean, in good repair and free of hazards.	42(b) - A resident may not be neglected, intimidated, physically or verbally abused, mistreated, subjected to corporal punishment or disciplined in any way. 42(c) – See above.
Resident is not receiving breathing treatments	-Resident's care needs and prescribed treatments	142(a) - The home shall assist the resident to secure medical care if a resident's health status declines. The home shall document the resident's need for the medical care, including updating the resident's assessment and support plan. 187(d) - The home shall follow the directions of the prescriber. 225(a) - A resident shall have a written initial assessment that is documented on the Department's assessment form within 15 days of admission. The administrator or designee, or a human service agency may complete the initial assessment. 227(d) - Each home shall document in the resident's support plan the medical, dental, vision, hearing, mental health or other behavioral care services that will be made available to the resident, or referrals for the resident to outside services if the resident's physician, physician's assistant or certified registered nurse practitioner, determine the necessity of these services. This requirement does not require a home to pay for the cost of these medical and behavioral care services.	23(a) - A home shall provide each resident with assistance with ADLs as indicated in the resident's assessment and support plan. 42(b) – See above.

Element	Corroboratory Information Required	Direct Regulatory Relationship 55 Pa. Code Ch. 2600	Indirect Regulatory Relationship 55 Pa. Code Ch. 2600
Resident climbs stairs with difficulty	Resident's mobility status	226(a) - The resident shall be assessed for mobility needs as part of the resident's assessment. 226(b) - If a resident is determined to have mobility needs as part of the initial or annual assessment, specific requirements relating to the care, health and safety of the resident shall be met immediately.	122 - Unless otherwise regulated by the Department of Labor and Industry, the Department of Health or the appropriate local building authority, all buildings must have at least two independent and accessible exits from every floor, arranged to reduce the possibility that both will be blocked in an emergency situation. 132(d) - Residents shall be able to evacuate the entire building to a public thoroughfare, or to a fire-safe area designated in writing within the past year by a fire safety expert within the period of time specified in writing within the past year by a fire safety expert. For purposes of this subsection, the fire safety expert may not be a staff person of the home.
Resident is not receiving therapy	-Resident's care needs -Resident's prescribed treatments	142(a), 225(a), 227(d) – See above.	23(a), 42(b) – See above.
Resident's needs cannot be met by the home	-Resident's care needs -Home's ability to meet needs	142(a), 225(a), 227(d) – See above. 223(a) - The home shall have a current written description of services and activities that the home provides including the following: (1) The scope and general description of the services and activities that the home provides. (2) The criteria for admission and discharge. (3) Specific services that the home does not provide, but will arrange or coordinate. 223(b) - The home shall develop written procedures for the delivery and management of services from admission to discharge. 224(a) - A determination shall be made within 30 days prior to admission and documented on the Department's preadmission screening form that the needs of the resident can be met by the services provided by the home.	None

Stage 3: Plan

Investigation Plan
Team Members: Inspector Jones, Inspector Pride

Information Collection Methods, By Element:

Element	Possible Methods
Food is bad	• Direct observation of physical plant • Staff interviews • Resident interviews • Conducting onsite inspection at mealtime
Food is cold	• Direct observation of physical plant • Staff interviews • Resident interviews • Conducting onsite inspection at mealtime
Resident lives in hazardous environment	• Direct observation of physical plant
Resident is not receiving breathing treatments	• Review of resident's record • Staff interviews • Resident interview • Collateral contacts with resident's primary care physician or pulmonologist
Resident climbs stairs with difficulty	• Direct observation of resident ambulating • Resident interview • Staff interviews
Resident is not receiving therapy	• Review of resident's record • Staff interviews • Resident interview • Collateral contacts with resident's primary care physician, physical therapist, and home health agency coordinating therapy
Resident's needs cannot be met by the home	• Comparison of home's criteria for admission and discharge with resident's preadmission screening • Comparison of home's written description of services with actual provision of care.

Distribution of duties, By Inspector:

<u>Jones</u>
Conducts resident interviews
Conducts staff interviews
Direct observation of mealtime activities, including food served

<u>Pride</u>
Reviews resident's record
Reviews home's criteria for admission and discharge

Reviews home's written description of services
Makes necessary collateral contacts relating to resident's care needs

Jones and Pride
Physical site inspection of basement area
Comparison of findings from above duties

Stage 4: Implementation

Self-explanatory

Stage 5: Modification

During Inspector Jones's observation of mealtime activities, he observes that staff persons are not washing their hands before serving food. When speaking to one of the staff about this practice, Jones observes an open sore on the staff person's left hand. Jones is concerned that the staff person may have a medical condition that prevents him from safely providing care to residents, and requests to see his record. He does not find evidence of a serious medical condition, but does find that his criminal background checks was disseminated by a private company instead of the Pennsylvania State Police. He determines through an interview with the home's administrator and a review of a sample of other staff records that no background checks are disseminated by the Pennsylvania State Police.

Stage 6: Timeline

The investigation began on June 14, 2012. Based on the investigation plan's findings, Jones and Pride were able to establish the following timeline:

Resident #1 was admitted on May 1, 2012 (resident-home contract) from an acute care hospital (preadmission screening). Prior to hospitalization, Resident #1 lived in his private home (preadmission screening). The resident was diagnosed with COPD while hospitalized and breathing treatments were ordered (Documentation of Medical Evaluation, contact with primary care physician).

As of June 14, 2012, the home made no efforts to assist Resident #1 in scheduling home health services to provide the prescribed breathing treatments (staff interviews, resident interview, record review, collateral contact with resident's health insurance company). The need for breathing treatments is not addressed on the resident's Assessment-Support Plan.

Upon admission, the resident did live in a room on the ground floor with exits to grade (resident-home contract), but was relocated to a room on the first floor in early June because using the stairs caused pain in his legs (resident interview).

The pain in the resident's legs is a chronic condition resulting from an injury sustained during the Vietnam War (resident interview), and is not prescribed to receive any therapy (Documentation of Medical Evaluation) except pain management medication, which are being administered correctly (staff interviews, Medication Administration Record).

The rooms on all floors of the home are free of hazards and appropriately heated (direct observation of physical plant).

The home does not have written criteria for admission and discharge.

The food served meets the minimum requirements of Chapter 2600, and is served at the appropriate temperature (direct observation, resident interviews). The staff person with the injured hand was hired on April 3, 2012 and has no chronic medical conditions (record review). On June 12, 2012, he cut his hand

on a pork bone; the cut became infected, resulting in the open wound observed by Jones on June 14, 2012 (staff interview). Kitchen staff do not follow a particular procedure relating to hand-washing, and do so as time allows because mealtimes are very busy (staff interviews).

The home uses a private, web-based service for all criminal background checks (record review, staff interview).

Stage 7: Timeline Analysis

Violations relating to the original complaint

142(a)
The home shall assist the resident to secure medical care if a resident's health status declines. The home shall document the resident's need for the medical care, including updating the resident's assessment and support plan.
Violation: The home did not assist the resident to secure breathing treatments ordered by his physician on April 30, 2012 at any time.

223(a)
The home shall have a current written description of services and activities that the home provides including the following:
(1) The scope and general description of the services and activities that the home provides.
(2) The criteria for admission and discharge.
(3) Specific services that the home does not provide, but will arrange or coordinate.
Violation: The home's written description of services and activities does not include criteria for admission and discharge.

227(d)
Each home shall document in the resident's support plan the medical, dental, vision, hearing, mental health or other behavioral care services that will be made available to the resident, or referrals for the resident to outside services if the resident's physician, physician's assistant or certified registered nurse practitioner, determine the necessity of these services. This requirement does not require a home to pay for the cost of these medical and behavioral care services.
Violation: The resident's Assessment-Support Plan did not address the need for breathing treatments.

Violations unrelated to the original complaint

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Criminal history checks and hiring policies shall be in accordance with the Older Adult Protective Services Act (OAPSA) (35 P.S. § 10225.101-10225.5102) and 6 Pa.Code Chapter 15 (relating to protective services for older adults).
Violation: The home's criminal history background checks are not obtained in accordance with Pennsylvania's Older Adults Protective Services Act. Pursuant to the Act, criminal background checks must be obtained from the Pennsylvania State Police database. The home uses a private company to generate background checks.

163(a)
Staff persons, volunteers and residents involved in the storage, preparation, serving and distributing of food shall wash their hands with hot water and soap prior to working in the kitchen areas and after using the bathroom.
Violation: Staff persons do not wash their hands do not consistently wash their hands before working with food or after using the bathroom.

163(d)
Staff persons, volunteers and residents who have a discharging or infected wound, sore, lesion on hands, arms or any exposed portion of their body may not work in the kitchen areas in any capacity.
Violation: "Staff person A" had a weeping sore from an infected cut on his left hand and was distributing food to residents.

Stage 8: Final Report

In this example, the inspectors' work product produced for Stages 1-7 were sufficient for internal reporting. A formal notice of violations was presented to the home in accordance with agency policy.

Conclusion

Unlike licensing inspections initiated by statutory or regulatory requirements (such as an annual inspection to determine whether a licensed setting continues to meet the requirements for licensure), regulatory investigations are initiated in response to a specific event, such as a complaint or an incident self-reported by a licensed setting. Regulatory investigations employ an 8-stage sequence called *tangential speculation*, which is the practice of associating events with regulations either directly or indirectly. Unlike "standard" investigations that take place outside of a regulated environment, tangential speculation may be applied in licensed settings because regulatory compliance is the expected norm.

As with all licensing activities, the primary purpose of the regulatory investigation is protection through prevention. By employing tangential speculation, the regulator works to identify and remediate noncompliant practices in licensed settings. The regulator's role is not to establish guilt for the purposes of punishment, but to ensure regulatory compliance to prevent future harm or mistreatment from occurring.

About this Document

This document was produced by Ronald Melusky, Director of the Commonwealth of Pennsylvania's Bureau of Human Services Licensing and President-Elect of the National Association for Regulatory Administration (NARA). The document has been reviewed and is endorsed by the National Association for Regulatory Administration, but does not necessarily reflect the views and opinions of the membership.

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